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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/514,626	06/23/2005	Finn Skou Pedersen	PEDERSEN10	7989

1444 7590 01/05/2010

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
01/05/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/514,626	PEDERSEN ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6-17,19,21,22,24,27-33,35-37,39,40 and 43-49* is/are pending in the application.

4a) Of the above claim(s) *11-17,19,21,22,24,27-33,35-37,39 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6-10,43-45 and 47-49* is/are rejected.

7)☒ Claim(s) *46* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 10/8/2009. The status of the claims is as follows: claims 4, 6-10 and 43-49 are under current examination and claims 11-17, 19, 21, 22, 24, 27-33, 35-37, 39 and 40 are withdrawn.

Any rejection(s) or objection(s) not reiterated herein has been withdrawn.

To allow entry of the rejection(s) set forth herein, the instant office action is non-final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6-10, 43-45 and 47-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a purified or non-naturally occurring mutant polypeptide comprising an amino acid sequence which is at least 95, 96, 97, 98 or 99% identical to the retroviral envelope polypeptide amino acid sequence shown in SEQ ID NO: 2 wherein said polypeptide is a) capable of mediating infection of a cell by use of the polytropic/xenotropic receptor encoded by the Rmc1 locus of the NIH Swiss inbred NFS/N mouse for entry and unable of mediating infection of a cell by use of a human polytropic/xenotropic receptor

encoded by the human RMC1 locus or b) capable of mediating infection of a human cell and wherein said polypeptide of (b) differs from SEQ ID NO:2 by at least one substitution in the VR3 region of SEQ ID NO:2.

The following quotation from section 2163 of the MPEP is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed or through disclosure of a functional characteristic of the claimed genus coupled with a known or disclosed non-functional characteristic (structure) that correlates to the function.

Structurally, as noted above, the claims are drawn to a purified or non-naturally occurring mutant polypeptide comprising an amino acid sequence which is at least 95, 96, 97, 98 or 99% identical to the retroviral envelope polypeptide amino acid sequence shown in SEQ ID NO: 2. Note that the sequence set forth by SEQ ID NO: 2 contains

639 amino acids in its entirety. A sequence which is at least 95, 96, 97, 98 or 99% identical to the 639 amino acid sequence set forth by SEQ ID NO: 2 allows for a 6 to 32 amino acid difference in homology. Further, as claimed, such an amino acid difference may occur at *any position* of the sequence wherein the differing amino acid may be *any one* of the existing 20 amino acids, each of which possesses differential properties, including space-filling volume, charge, hydrophobicity, psi/pfi angles etc.

Functionally, the claims are drawn to a polypeptide that is a) capable of mediating infection of a cell by use of the polytropic/xenotropic receptor encoded by the Rmc1 locus of the NIH Swiss inbred NFS/N mouse for entry and unable of mediating infection of a cell by use of a human polytropic/xenotropic receptor encoded by the human RMC1 locus or b) capable of mediating infection of a human cell and wherein said polypeptide of (b) differs from SEQ ID NO:2 by at least one substitution in the VR3 region of SEQ ID NO:2. Note that while the claims are drawn to a wide scope of polypeptides in view of the claimed structure, the claims are drawn to polypeptides comprising specified functions (e.g. infection via binding of a specific receptor).

The instant specification provides support for a number of mutations/substitutions including those found in Table 8 but such double mutants merely provide substitutions at positions 212/213 and such substitutions only contain a select few of amino acids. In addition, the specification fails to provide a structure to function correlation which supports the wide scope of different polypeptides as claimed wherein the polypeptides have at least 32 amino acids that are not homologous to the sequence set forth by SEQ ID NO: 2 at any site of the sequence using any amino acid that are capable of

performing the specified functions as claimed. It is noted that some non-homologous amino acids at some sites may produce steric effects, affecting the overall structure and function of the protein; see instant specification which describes steric problems which may affect the binding of the protein to a specific receptor by introducing an amino acid with a small side with one that has a larger space-filling volume (p. 8, lines 29+). This issue, however, was further ascertained. Separately, the prior art teaches that a substitution of a single amino acid may affect both the structural folding and function of the protein (see Bowie et al., *Science*, 1990).

In view of the wide scope of the polypeptide structures claimed and the lack of support provided by the instant specification in disclosing any structure to function correlation, the claims are rejected as lacking adequate written description in the instant specification.

Allowable Subject Matter

Claim 46 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Primary Examiner, Art Unit 1648